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TITLE: Diabetes Care and Treatment Project: A Diabetes Institute of the Walter Reed Health Care System and Joslin Telemedicine

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14. ABSTRACT: The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the care process, that empowers the patient to better manage their disease, that can be performed in a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research will be to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable, but it is treatable, and its complications are preventable. The primary goal of treatment is to manage diabetes to live a healthy life. In general, the traditional physician-centered, episodic, acute-care model is not designed to care for large numbers of diabetic patients (more than 2,200 new cases diagnosed every day in the US) and in order to meet this challenge the health care delivery system will need to be re-engineered. This can become a reality with the use of the CDMP developed under this collaborative effort.					
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Statement of Work

The research proposals described below will leverage the successful deployment of the Joslin Vision Network (JVN) Eye Health Care program and the integration of the Comprehensive Diabetes Management Program (CDMP) to provide continuum of care for diabetic patients. The CDMP application has been developed under this collaboration and represents participation and input from leading experts in diabetes care from the Joslin Diabetes Center, Department of Defense, and the Veterans Health Administration.

Various studies have been deemed critical in order to provide the medical evidence to support preliminary data and expectations that this program will provide significant reductions in health care dollar expenses while maintaining a high quality of care as assessed through a reduction in complications such as blindness from diabetes. The expectation is that the use of this program will also increase the access of patients to appropriate care and provide a very powerful tool that will empower the patient to improve their own management of their diabetes.

The studies proposed in this continuing proposal are prospective in nature and involve the multiple participating centers. The planning and rigorous study design development will be undertaken during the first 6 months of this study. Additional effort will be spent on the establishment of the study coordination center, the development of the appropriate database and the development of a clinical study module for the CDMP.

These proposed prospective studies will require 3 to 4 years for successful completion. The different studies are enumerated in the following Statement of Work (SOW):

1. Prospective multi center cost efficiency study performed using the JVN Telehealth Eye Care module
2. Prospective multi-center risk benefit study using the JVN Telehealth Eye Care module
3. JVN Telehealth CDMP program usability and impact on clinical workflow study
4. Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program
5. Clinical validation of the Behavior Assessment Tool (BAT) developed for the JVN Telehealth CDMP application
6. Deployment of JVN Telehealth CDMP application into the Department of Defense TRICARE Online computer system

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Background

Diabetes Mellitus (DM) is a prevalent costly condition that causes significant morbidity and mortality. In the United States nearly 21 million people or 7% of the total population have diabetes and of whom at least 6 million are undiagnosed. An additional 41 million people are estimated to have pre-diabetes. Diabetes is the sixth leading cause of death in the United States. Consistent with devastating personal effects of diabetes, the costs to the health care system were estimated at \$132 billion in 2002 (\$92 billion in direct medical costs and \$40.8 billion, including 88 million disability days and 176,000 cases of diabetes related disability, in indirect costs) compared to \$98 billion in 1997. The per person expenditures for managed care organization members with diabetes is 2.4 times higher than those without diabetes. There is abundant evidence and documentation that diabetes is a major component of all health care expenditures in the United States with most of this cost associated with long term complications of diabetes specifically, retinopathy, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease resulting in amputations.

Traditional health care delivery involves individual providers reacting to patient-initiated complaints and visits. Care is often fragmented, disorganized, duplicative, and focused on managing established disease and complications. Management of the disease is provider directed and focuses on pharmacologic and technologic interventions with little attention to patient self-management behaviors and provider-patient interactions (6). Evidence shows that improving care for diabetic patients results in cost savings for health care organizations and recent economic analysis studies have shown that diabetes eye care and preconception care were found to be cost saving. Additionally, preventing neuropathy and improving glycemic control also were found to be cost saving .

Despite advances in treating these complications, efforts aimed at prevention are the best approach to reduce morbidity and mortality.. In the last decade, innovative interventions for health care delivery have emerged that show promise for improving care, outcomes and costs for individuals and populations with diabetes. Disease and case management are two interventions that continue to demonstrate considerable potential and promise. In the arena of prevention, objectives 5-11 through 5-15 of the *Healthy People 2010* for the United States directly relate to improving screening for complications involving the retina, the kidney, the extremities, the oral cavity and the monitoring of glycemic control.

Two problems to overcome in order to reduce or prevent diabetic complications are (1) providing access of all diabetic patients to proven diagnostic and treatment strategies which reduce the risk of vision loss and (2) identifying effective methods to improve the metabolic control of patients with diabetes to reduce the risk of chronic complications. The challenge to overcome these problems is formidable. For example, intensive research over the last 30 years has developed methods that virtually eliminate diabetic retinopathy as a cause of severe vision loss. Nevertheless, diabetes remains the leading cause of new blindness in working-aged adults in the United States. The reason for this incongruity is many patients do not receive quality eye care because of geographical barriers, insufficient health insurance or financial resources, or patient or health care provider ignorance.

In a review article aimed at examining the effectiveness of disease management and case or care management for people with diabetes, the authors found that disease and care management was effective as interventions when delivered concurrently and also when delivered in conjunction with educational interventions, decision support and reminders on performance issues, such as, timely retinal evaluation. These authors went on to indicate that one of the most pressing needs is to better define effective interventions as disease management has multiple component interventions. It may be that for the optimal

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use of resources only the interventions that contribute the most to positive outcomes need to be implemented. These interventions have yet to be defined. Additional research will need to be done, however, to identify the optimal intensity and frequency of these interventions as well as a consideration of whether professionals other than nurses (social workers, health aids or pharmacists) can function as care managers. Other research areas of importance were identified as: consideration of integration of disease management into existing health care systems, the effect of disease and care management on long-term health and quality of life outcomes, such as, cardiovascular disease events, visual impairment, amputations, renal failure and mortality, and the effect of care management on blood pressure, weight, lipid levels and provider screening rates for retinopathy, peripheral neuropathy and microalbuminuria. Finally this review was unable to identify any appropriately rigorous studies aimed at evaluating the cost effectiveness of the care management intervention.

This annual report for the ongoing JVN Telehealth program at WRAMC provides an overview and status report of the studies designed to address the research questions posed above. This telehealth initiative is a unique opportunity to leverage the technological developments achieved over the past 5 years in the development of the JVN eye care and disease management programs to provide evaluations of the multiple diabetes disease management interventions from a single unified platform, the JVN Comprehensive Diabetes Management Program. The implementation of the JVN programs is extraordinarily timely in light of a recent publication in the Journal of the American Medical Association promoting the use of organized care management processes to improve the health care quality for patients with chronic diseases. The authors conclude that, although the use of care management processes vary greatly among physician organizations, the usage is low on average. They call on government and private purchasers of health care to increase the usage of care management processes through provision of external incentives for improvement of health care quality and to promote and assist physician organization to increase or improve their information technology capabilities. This continuation proposal is positioned to allow participants to play a lead role in developing evidence from rigorous multi-center studies to further support these recommendations.

Research Plan

Hypotheses

We hypothesized that implementation of the Joslin Vision Network Telehealth Program would result in increased clinical effectiveness and economic efficiency through the use of disease management and care management for people with diabetes. Additionally the use of the JVN program would result in a marked decrease in vision loss secondary to diabetes, improved management of diabetes with resultant decrease in mortality and morbidity, a reduction in patient associated emotional stress in dealing with their own diabetes, an increase in patient and provider satisfaction, and attendant cost-savings in the management of a chronic disease. The use of telemedicine here would enable the care management follow-up and coordination to take place easily over wide geographic areas.

Summary of Research Plan

The appropriate study designs for the prospective studies outline below have been completed. This planning period involved focused working groups developing and finalizing study designs, submission of protocols to the appropriate agency Investigational Review Boards for approval and the writing of the different Manuals of Operations for the different studies. The studies and related work that were conducted during 2006 are outlined below:

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1. Prospective multi center cost efficiency study performed using the JVN Telehealth Eye Care module. The primary questions are:
 - a. What are the costs associated with diabetic retinopathy evaluations performed by an Ophthalmologist with a dilated eye examination and the JVN system using digital video imaging through an undilated pupil?
 - b. What is the cost-effectiveness of ophthalmoscopy performed by eye care professionals compared to the Joslin Vision Network?
2. Prospective multi-center risk benefit study using the JVN Telehealth eye care module. The primary question for this study is:
 - a. What is the frequency and duration of JVN examinations for diabetic retinopathy determination as compared to current clinical guidelines of a dilated eye examination performed annually by an Ophthalmologist with expertise in diabetic retinopathy?
 - b. The frequency will be dependent on the relative diabetes risk status of the patient as determined through the use of the CDMP system.
3. JVN Telehealth CDMP program usability and impact on clinical workflow study. This study focused on investigating the level of patient and provider satisfaction as well as the optimum positioning of the CDMP disease management and care management process within the overall clinical workflow process.
4. Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program. This study will investigate:
 - a. The economic efficacy of disease and care management using the CDMP application compared to traditional care management of diabetic patients.
 - b. The clinical outcomes associated with development of diabetes complications, behavior modification and emotional stress in dealing with diabetes, and the efficacy of different educational interventions.
5. Clinical validation of the Behavior Assessment Tool developed for the JVN Telehealth CDMP application. To develop a reliable and valid instrument to assess diabetic patients' current behaviors and patient issues associated with improving their own ability to better manage their own diabetes.
6. Development and validation of Learning Level Assessment and Readiness to Learn tools for the JVN Telehealth CDMP application. The primary objectives of this study are to:
 - a. Develop a reliable and valid instrument for the assessment of Learning Level and readiness to learn.
 - b. Evaluate appropriate educational interventions and the frequency of such interventions.
7. Deployment of JVN Telehealth CDMP application into the Department of Defense CHCS II and into the TRICARE Online computer system. Development of Standard Operating Procedures for integration of the CDMP application into the existing portal for the TOL system.

Methodology

The studies outlined below were aimed at evaluating the clinical benefit and economic efficacy of the usage of the JVN Telehealth program using results from sites participating in the program. Interventions for diabetes use current economic resources to obtain future benefits where cost-saving or cost-effective interventions can

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prevent the economic impact of long term complications such as blindness, end stage renal disease, and lower extremity amputations as well as short term complications such as hospitalizations for poor glycemic control. The expectation from the results of the studies is that preventive care of diabetes is a prudent allocation of health care dollars. Additional value is added in performing analyses on the effectiveness of the above interventions using a single integrated platform that provides for the collection of all the data elements that will be needed for these analyses. There is a very real advantage for the use of a single application that can be used to both assess total disease management and provides the ability to stratify the data to investigate different interventions as isolated phenomena.

In order to successfully design the appropriate studies for the economic and clinical outcomes analyses of the various components of the JVN Telehealth program the first six months on this continuation was spent on developing the study designs and study processes. This design period incorporated the participation of the different Principal Investigators associated with the project in focus working group sessions at fixed sites. Our experience to date, especially with the design of the CDM application itself, was that this mode of operation was very effective and very productive. The deliverable at the end of this study design period will be documentation on the appropriate randomized controlled studies that will be performed under this collaborative funding vehicle. Of necessity then, the study protocols presented below are intended to demonstrate potential design paradigms that will provide the starting points for the working sessions.

Outcomes for disease management and case management also involve the health care system, provider and patient or population. These outcomes are summarized in Table 1 and are related to health and quality of life metrics. The study elements that will be examined in evaluating these clinical and economic interventions are summarized below:

1. Target population; Patients eligible for a particular intervention
2. Screening method: procedure used to detect condition selected for intervention
3. Screening schedule: time interval between repeated screening procedures
4. Treatment population: patients receiving the intervention
5. Treatment method: treatment intended to provide future benefits in exchange for current economic resources
6. Baseline program: the standard treatment or lack of any treatment, to which the treatment method is to be compared
7. Types of costs: the categories of expenses associated with an intervention and its outcome such as direct costs, indirect costs, disability payments, hospitalizations, length of stay etc
8. Year of costs: the year in which costs were incurred or the final year of an intervention whose costs were incurred over multiple years
9. Discount rate: the devaluation rate for future costs or benefits
10. Costs or Savings: the net costs or savings of an intervention compared with the baseline program
11. Benefits: the health outcomes of an intervention compared with the baseline program
12. Cost-Benefit ratio: the cost of an intervention divided by the benefit gained
13. Sensitivity analysis: a recalculation of the cost-benefit ratio that substitutes an estimate of a cost or benefit with an alternate estimate in a modeling study
14. Perspective: the party, such as the Federal Agency or society, who pays the costs and accrues the benefits of an intervention.

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Table 1: Summary of Outcomes to be evaluated for analyses of CDMP disease and care management application.

Patient	Intermediate (process) outcomes Provider	Healthcare system
Patient knowledge	Provider participation	Health insurance Coverage, adequacy
Patient skills	Provider satisfaction	Provision of services
Problem-solving skills	Provider productivity	Regular source of care
Self-monitoring blood glucose	Number of patients seen	Regular visits
Medication administration (including insulin)		Availability of patient education
Psychosocial outcomes	Screening and monitoring	Health care utilization
Self-efficacy	Blood pressure	Number of admissions
Health beliefs	Glycemic control	Number of out-patient visits
Mood	Lipid levels	Length of stay
Attitude	Retinopathy	
Coping skills	Peripheral neuropathy	
Self-assessed health status	Microalbuminuria	Public health services
Locus of control	Weight	Availability
Perceived barriers to adherence		Quality
Patient satisfaction with care	Provider treatment	
	Glycemic control	
	Cardiovascular disease	
	Hypertension	
	Nephropathy	
	Neuropathy	
	Retinopathy	
	Vaccination: pneumococcal, influenza	
	Use of ACE inhibitors	
	Use of aspirin	
Short-term outcomes Patient	Patient	Long-term outcomes Healthcare system
Glycemic control	Macrovascular complications	Economic outcomes
Glycated hemoglobin	Peripheral vascular disease	Outpatient utilization
Fasting blood glucose	Coronary heart disease	Hospitalization rates
	Cerebrovascular disease	Cost
Physiologic outcomes	Microvascular complications	Cost-effectiveness/benefit
Weight	Decreased vision	
Lipid levels	Peripheral neuropathy	
Foot lesions	Renal disease	
Blood pressure	Foot ulcers	
Microalbuminuria	Amputations	
Retinopathy	Periodontal disease	
Lifestyle	Mortality	
Physical activity	Quality of life	
Diet	Disability/function	
Smoking		
Substance abuse		
Mental health	Pregnancy-related outcomes	
Depression	Neonatal morbidity and mortality	
Anxiety	Maternal morbidity	
Work-related		
Work days lost		
Restricted duty days		

Summary of Projects and Methods for Individual Projects as Identified in the Statement of Work.

1. Prospective Economic Analysis of the Joslin Vision Network (JVN) Telehealth Eye Care Module.

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Principal Investigators: Robert A. Vigersky, MD, John David Whited, MD, MHS, Co-Investigator: Stephanie Fonda, PhD

Objective: This study has tremendous potential and importance and it will be a landmark evaluation for this type of technology. The goal of this study is to collect prospective data on incurred costs and observed outcomes that will be analyzed using a decision analytic model. The following research questions will be answered.

Research Questions

(1) What are the costs of screening for diabetic retinopathy with ophthalmoscopy (Dilated Fundus Examination performed in an Ophthalmology/Optomtery office and a “screening” approach that would be a dilated but limited eye examination performed by the Ophthalmologist/Optomterist) performed by eye care professionals and with the Joslin Vision Network?

(2) What is the cost-effectiveness of ophthalmoscopy performed by eye care professionals compared to the Joslin Vision Network? Measures of effectiveness include (a) the observed number of patients referred and treated with laser photocoagulation for diabetic retinopathy and (b) the imputed number of cases of severe vision loss averted with the following breakdown of measures:

- a. How does JVN compare with Dilated Fundus Exam for
 - i. Referral to laser
 - ii. Actual receipt of laser
- b. How does JVN compare with Dilated Fundus Exam for
 - i. Estimated Severe vision loss (SVL, 5/200)
 - ii. Estimated moderate vision loss (MVL, More than just SVL...need to include MVL, legal blindness, person years sight saved, annual cost savings, Doubling of visual angle)
- c. How does JVN compare to Dilated Fundus Exam for
 - i. Cost per patient referred to laser
 - ii. Cost per patient receiving laser
 - iii. Cost per person sight saved for Severe Vision Loss (SVL)
 - iv. Cost per person sight saved for Moderate Vision Loss due to macula edema (MVL)
 - v. Cost per total sight saved
- d. Calculations will also include the following time elements
 - i. How does JVN compare to Dilated Fundus Exam for time to screen each patient
 - ii. A comparison of total throughput savings for each of above

Study Design and Methodology

Subjects: Study subjects include patients with either type 1 or type 2 diabetes mellitus that are followed by one of the participating clinic sites. Eligible subjects are those that are recommended to undergo annual eye examinations. Patients with diabetes without evidence of clinically significant retinopathy, both male and female over the age of 18, will be recruited from Walter Reed Army Medical Center and clinics in the WRHCS.

Study Design: Our study design is a multi-site randomized clinical trial. Observed data generated from the randomized trial in combination with literature-based, epidemiologic, and administrative data will be integrated into a decision analytic model using Data TreeAge Pro (TreeAge Software, Inc., Williamstown, MA, USA). Patients with type 1 or type 2 diabetes mellitus will be randomized to conventional clinic-based eye examinations or eye examinations performed by the JVN. The JVN examination includes an assessment of

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visual acuity in addition to the images and clinical data generated by the JVN. The study will use existing JVN teleophthalmology consult systems deployed at WRAMC and affiliated clinics. Each system includes JVN image acquisition workstations and a reading center workstation. Clinic-based eye examinations are being performed at the WRAMC or MTF Ophthalmology/Optometry Clinic. Patients enrolled in the study will be followed for 12 months from the date of enrollment. Therefore, in our base-case analysis, all costs and clinical outcomes will be annualized. In the JVN camera analysis, standard modified Airlie House classification for retinal grading will be used as follows:

- Grade 1- no diabetic retinopathy.
- Grade 2- mild to moderate nonproliferative diabetic retinopathy.
- Grade 3- severe nonproliferative diabetic retinopathy
- Grade 4- very severe nonproliferative diabetic retinopathy.
- Grade 5- proliferative diabetic retinopathy.
- Grade 9- ungradeable (for camera images only).

Grading of maculopathy will be done separately in patients with any level of DR. Macular thickening is classified as no thickening, macular edema but not clinically significant, or clinically significant macular edema (CSME). The clinic examination diagnoses for retinopathy and referral to the retinal service will be done using standard clinical criteria.

We will compute and compare the cost to perform eye examinations in our randomized population with each examination modality. Costs will be correlated with our observed and imputed effectiveness measures. Measures of effectiveness include: (1) observed and imputed number of patients diagnosed with diabetic retinopathy or macular edema, (2) the observed and imputed number of patients treated for diabetic retinopathy or macular edema, and (3) the imputed averted cases of severe vision loss calculated by using literature-based epidemiologic parameters to extrapolate the study sample to the target populations of interest with diabetes mellitus. Costs will be correlated with effectiveness to generate cost-effectiveness ratios. Additionally, Markov modeling with Monte Carlo simulation will allow us to project costs and outcomes beyond our observed base-case 12-month analysis. Finally, in a cost-consequence analysis we will compare aggregate costs and outcomes between the two study arms. A cost-consequence analysis will allow us to report collective costs and outcomes without regard to specific disease entities or treatment options. This is a particularly important design element in terms of disease entities identified or suspected. Since we can't *a priori* predict the gamut of eye disease identified or suspected, this allows us to account for outcomes in an aggregate manner.

Sample size

Table 2 describes the number of study subjects needed per study arm and the total number of subjects required for enrollment if we wish to detect a 30% difference in compliance and smaller differentials. The sample size estimates are based on the z statistic to compare proportions of dichotomous independent variables using a two-tailed alpha of 0.05 and a power of 80%. The second column represents the minimum number of subjects required in each study arm. The third column represents the total number of subjects required, including an over-sampling rate of 25%. Over-sampling is required to insure that the minimum number of subjects is enrolled in each study group and to account for loss of follow-up, withdrawals, etc.

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Table 2. Sample size estimates based on differential compliance rates.

Expected Difference in Compliance	N per study group	Required Total Enrollment*
30%	42	105
25%	61	153
20%	97	243
15%	173	433
10%	387	968

* Sample size doubled to account for both study arms and increased by 25% for loss of follow-up, withdrawals, etc.

Using the mid-range compliance differential of 20%, we propose to enroll at least 243 subjects in the study.

Data analysis

Analysis Summary

The directly observed event probabilities, interventions, and cost elements will be used with literature-based estimates, epidemiologic data, and administrative data to design decision analytic models that output cost-effectiveness data. The tables are composed of observed event probabilities (e.g., the probability that patients in both study arms present for their examinations), observed diagnostic and management outcomes (e.g., the number and proportion of patients diagnosed with proliferative diabetic retinopathy and receive laser photocoagulation), and costs including directly observed cost elements (e.g., time studies used to calculate average labor costs). The decision models will extrapolate our findings to the two target populations – the WRAMC and WRAMC-affiliated clinic population with diabetes mellitus and the in-nation Department of Defense population, dependents, and retirees. Decision models will be constructed using TreeAge Pro (TreeAge Software, Inc., Williamstown, MA, USA).

A cost analysis and cost-effectiveness analysis will be performed. (Table 3) Unless one strategy shows dominance, cost-effectiveness ratios will be calculated. Analysis of costs and outcomes observed in the study population will consider the economic perspectives of the health care agencies and society.

Table 3. Summary of Perspectives and Populations for Reporting Cost-effectiveness Outcomes.

Effectiveness Measure	Economic Perspective		Population with Diabetes Mellitus Analyzed	
Diagnosis of diabetic retinopathy or macular edema	Health Care Agency	Society	WRAMC and affiliated clinics	In-nation DoD population
Treatment with laser photocoagulation	Health Care Agency	Society	WRAMC and affiliated clinics	In-nation DoD population
Severe vision loss averted	Health Care Agency	Society	WRAMC and affiliated clinics	In-nation DoD population

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Cost-effectiveness Analysis

The decision models generate cost-effectiveness tables for each measure of effectiveness and analytic case. Cost-effectiveness tables display average and incremental costs and outcomes for the population of interest. An intervention is dominant when it is both less costly and more effective. In the case of dominance, cost-effectiveness ratios are neither valid nor necessary. In the more usual case, one intervention is more costly but results in a greater level of effectiveness. A cost-effectiveness ratio is then calculated to describe the incremental costs that must be expended to derive the incremental benefit. A generic version of a cost-effectiveness table using hypothetical data appears below in Table 4.

Table 4. Template of cost-effectiveness table construction using hypothetical data.

Examination Modality	Cost of annual eye examinations	Incremental cost of annual JVN examinations	Patients diagnosed with proliferative diabetic retinopathy	Incremental patients diagnosed with proliferative diabetic retinopathy by JVN	Incremental cost-effectiveness ratio
Clinic-based eye examinations	\$800,000		24		
JVN	\$1,000,000	\$200,000	28	4	\$50,000

The interpretation of this table and cost-effectiveness ratio is as follows: Using the JVN as an alternative to clinic-based eye examinations for performing annual eye examinations would cost an additional \$50,000 per additional patient diagnosed with proliferative diabetic retinopathy. In other words, it “costs” \$50,000 to diagnose each additional patient with proliferative diabetic retinopathy. Policy decisions are based on this trade-off between cost and outcomes. When an intervention is dominant (i.e., both more effective and less costly) the policy implications are self-evident.

Observed Data Analysis

Table 5 summarizes the data elements that will be observed and directly collected. These data elements will be used for input into the decision analytic models. Observed outcomes include compliance rates, diagnostic categories, time studies, travel data, and treatment outcomes. As indicated in Table 1, cost-effectiveness ratios will be considered for diabetic retinopathy (all grades), proliferative diabetic retinopathy, macular edema (all grades), and clinically significant macular edema. Average and incremental costs per patient will be derived for the study sample and used to generate the cost-effectiveness data.

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Table 5. Summary of prospectively collected or observed data.

Date Element	Data Source	Data Output
LABOR COSTS		
JVN Imager	Time studies	Cost per unit time
JVN Image Reader	Time studies	Cost per unit time
Ophthalmologist/Optomtrist Exam	Time studies	Cost per unit time
Ophthalmic Technician Exam	Time studies	Cost per unit time
TRAVEL COSTS		
Travel Distance	Patient Questionnaire	Reimbursement rate per mile
Travel Time	Patient Questionnaire	Lost wages/productivity
DIAGNOSTIC OUTCOMES		
No Diabetic Retinopathy	Observed diagnoses	Event count
Any Diabetic Retinopathy	Observed diagnoses	Event count
Proliferative Diabetic Retinopathy	Observed diagnoses	Event count
No Macular Edema	Observed diagnoses	Event count
Any Macular Edema	Observed diagnoses	Event count
Clinically Significant Macular Edema	Observed diagnoses	Event count
Other	Observed diagnoses	Event count categorized by unique diagnosis
REFERRAL (EYE CARE CLINIC VISIT) RATES		
Clinic Visits for Eye Care	Observed visits	Event count
TREATMENT OUTCOMES		
Panretinal Laser Photocoagulation	Observed events	Event count
Focal Laser Photocoagulation	Observed events	Event count
Other Treatment	Observed events	Event count categorized by unique treatment regimen
COMPLIANCE		
Compliance with annually recommended eye exam per modality	Observed events	Compliance rates
Compliance with follow-up exams or treatment plans	Observed events	Compliance rates

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Imputed Data Analysis

In our imputed analysis we will extrapolate the findings from our study population to the two target populations. This is necessary to allow us to project diagnostic incidence rates and rates of severe vision loss averted. Using literature-based estimates of progression to severe vision loss, we can impute expected severe vision loss events in each study arm.

Economic Perspective

We will take two economic perspectives in our analyses. Our first economic perspective is based only on those costs incurred by the WRAMC and the DoD. Our second, and arguably most important perspective, is the societal perspective. All identified costs to society at large, regardless of who bears the cost, will be considered in this analysis.

Cost Consequence Analysis

The cost consequence analysis will not be restricted to our *a priori* diagnostic categories of diabetic retinopathy and macular edema. We will generate a listing of all diagnostic categories diagnosed by the JVN and clinic-based eye examinations as recorded by the CDMP. In a similar manner, we will generate the total costs incurred by our patient sample in each treatment arm (i.e., the total costs of observed repeat examinations, clinic-based visits, treatments, etc.). Because randomization will most likely result in patient samples that are slightly different in number, we will calculate per-patient eye disease rates and average costs in order to allow for direct comparison between our two groups.

Sensitivity Analysis

We will conduct both model and variable sensitivity analyses, as necessary. Model sensitivity analysis is performed using alternative modeling assumptions when different sequelae are possible. Variable sensitivity analysis analyzes the base-case model point estimate data (variables) with a range of plausible, expected, or observed data (range of variables). We will perform one-way sensitivity analysis (i.e., one variable at a time) to identify those variables that may significantly affect the base-case results and, if indicated, conduct multi-way sensitivity analysis on identified variables. We will also use Monte Carlo simulation to estimate the precision (i.e., confidence interval) of the cost-effectiveness ratios.

KEY RESEARCH ACCOMPLISHMENTS:

Rigorous study design completed. The study protocol was approved by the Walter Reed Army Medical Center (WRAMC) Human Use Committee (HUC)/IRB and recruitment began in September 2006. At the time of this report, the following has been achieved:

- 120 patients, nearly half the recruitment goal, have been enrolled into the JVN Economic Analysis study with approximately 50% randomized into each of the two arms.
- Two ophthalmologists and two optometrists have been trained by Joslin Diabetes Center in Boston to read the images.
- An additional imager was trained by the Joslin Diabetes Center in Boston to obtain images for a total of 5 trained imaging technicians.

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- Two reader and four imaging workstations have been successfully upgraded to the JVN 4 system. The two reader workstations are in the Department of Ophthalmology at WRAMC and in Department of Optometry at KACC
- Imagers and imaging workstations are located at WRAMC, KACC, DeWitt, and the Fairfax Family Health Center.
- An additional imaging workstation, located in the White Flint Professional Building, Rockville, MD, is being used for another study being conducted by the DI.

2. The Usability and Workflow Impact on Diabetes Care Specialists of the Comprehensive Diabetes Management Program (CDMP). Investigators: Robert A. Vigersky, Jill Phillips, Director HealtheForces, David Rodbard, American Institutes for Research, and Stephanie Fonda, Joslin Diabetes Center.

This project will examine the usability and impact on clinical workflow of a new health information technology (HIT): a web-based Comprehensive Diabetes Management Program (CDMP). The CDMP is a new, interactive, web-based tool for physicians, care managers and people with diabetes. The project will examine the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline HIT system in the Walter Reed Army Health Care System (WRHCS). The original goal of the study was to: (1) examine the Diabetes HealtheCard data (which documents the process and quality measures of the Diabetes Quality Improvement Program (DQIP) of selected diabetes health care providers and administer questionnaires regarding aspects of the diabetes care system before and after adoption of the CDMP; (2) evaluate the use of the CDMP by observing the interactions of these care providers with standardized patients (i.e., actors who have been trained to provide a realistic initial or follow-up history for a simulated patient), and (3) use structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study were the Nurse Practitioners (NPs) of the Diabetes Institute of the WRHCS, all of whom have participated in developing the CDMP over the past two years. We received approval for this protocol and planned to conduct the research and initial data analyses in one year.

KEY RESEARCH ACCOMPLISHMENTS:

- Study subjects (diabetes nurse practitioners) were trained in the use of CDMP in May 2005 and again in June 2006
- Data collection was conducted between July and November 2006.
- Data collection was complicated by the discontinuation of HealtheForces (HeF) Integrated Clinical Data Base (ICDB) which was the WRHCS' unique HIT system and the introduction of AHLTA, the new military electronic medical record (EMR) system.
- Implementation of AHLTA coincided with the implementation of CDMP, thus requiring the NPs (study subjects) to use two new information systems almost simultaneously.
- The NPs generally felt that both systems were more cumbersome to use than HeF. Compounding the difficulty was the lack of a program that could electronically extract the data from AHLTA.
- Data was manually extracted by 4 research staff members in the DI. Despite every attempt to standardize data extraction, variations among the data extractors no doubt had some impact on the quality of the data to be analyzed.

Preliminary results indicated that:

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1. Factors above and beyond the control of either the CDMP group at Joslin or the research group in the WRHCS Diabetes Institute delayed the start of the study and complicated the original plan including numerous integration problems with AHLTA that complicated the efficiency and accuracy of CDMP.
2. Difficulties with CDMP itself included:
 - a. the reappearance and/or inaccuracy of alerts and reminders once they had been turned off
 - b. the use of pick lists or other “discrete” data entry that were too limiting or restrictive.
 - c. the perception by all the NPs that CDMP was perceived as a tool that was better suited to case managers or primary care providers than for diabetes specialists.
 - d. inaccuracy of significant patient information, such as current medications, as a result of inaccuracy in data stored in AHLTA. In part this was related to the fact that many patients have multiple providers, including civilian providers, and it is a formidable task to maintain accurate medication records.

Recommendations included:

1. Interviews or focus groups with users at other locations, such as the Boston VA Hospital, the Joslin clinic, or the group in Hawaii could be conducted to explore whether the problems encountered at WRAMC are specific to WRAMC or whether they are more general.
2. Comparisons of results of the NP focus groups with ‘expert heuristic review’ of the CDMP by usability experts at AIR, and with the results of the usability laboratory studies conducted by AIR with nurses as the study participants.
3. Incorporation of the results from the CDMP usability and clinical workflow analyses into a revised version of the CDMP and into the manual of operations for the different proposed studies using the CDMP.
4. Comparison of the implementation and use of CDMP at WRAMC and use and implantation of CDMP in other systems.

The proposed multicenter study described below will only be initiated after completion and code rewrite of the CDMP usability and workflow study.

3. Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program: Improving Outcomes in Patients with Type 1 and 2 Diabetes by Using a Comprehensive Diabetes Management Program (CDMP) in the Primary Care Clinics of the Participating Agencies and the Joslin Diabetes Center.

P. I.: Robert A. Vigersky, M.D. COL MC., Paul R. Conlin, James L. Rosenzweig MD, Sven-Erik Bursell PhD, D. Peters, PhD. Co-Investigator: Stephanie Fonda, Ph.D.

Specific Aims: The goal of this study is to determine whether or not the use of information technology by primary care physicians in the Walter Reed Health Care System (WRHCS) and other participating agencies and institutions can improve outcomes in patients with both type 1 and type 2 diabetes mellitus. The WRHCS is an integrated population-based primary and specialty military health care provider for active duty service members, families and retirees in the National Capital area. The specific aims of this study are to determine:

- 1) The efficacy, safety, and acceptance of a comprehensive diabetes management program (CDMP) enhanced by a **computer assisted decision support system (CADS)** which will analyze blood glucose data and provide recommendations for management in improving outcomes in patients with diabetes mellitus when utilized by primary care providers (PCPs) including general internists, family practitioners, nurse practitioners, and physicians assistants.

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- 2) Whether or not further improvement in glycemic control can be obtained by providing primary care providers and their patients with a web-based blood glucose data monitoring and analysis (GDMA) system with some providers having access to CADS which will provide an automated interpretation of their patients' glucose profile and recommendations for therapy (either insulin dose adjustment or alteration in oral medication).
- 3) Whether clinically and statistically significant improvement in glycemic control can be sustained for up to 3 years;
- 4) Whether there is a decrease in the number of major and minor hypoglycemic episodes, emergency room visits for diabetes-related causes, and hospitalizations and hospital days for diabetes-related illnesses
- 5) Whether or not there is improved adherence to generally accepted clinical practice guidelines
- 6) Whether there is an improved quality of life for patients with diabetes mellitus.

We will compare patients whose providers are using CADS with those receiving "usual care" by these same providers. Patient-related parameters that will be examined include Hemoglobin A_{1c}, mean (+/- std. dev. and +/- sem) blood glucose values, the total number of office visits and telephone consultations/e-mails, and compliance with scheduled office visits, laboratory testing, and with medication and treatment regimens. Similarly, we will analyze the compliance with the Diabetes Quality Improvement Project (DQIP - a set of minimum criteria for performance reporting of diabetes care¹) and the adherence to the clinical practice guidelines of the DoD/VHA, American Diabetes Association (ADA), and American Association of Clinical Endocrinologists (AACE) in physicians who have or have not had the access to CDMP or CDMP + CADS with those providing "usual care".

Dissemination and Sustainability: If the present project demonstrates improved quality of care and clinical outcomes for patients with diabetes mellitus, the use of this approach will be sustained within the WRHCS for patients followed by primary care providers as well as those followed by endocrine/diabetes specialists and sub-specialty nurse practitioners. We estimate that this would affect approximately 6,000 patients with diabetes. The expenditures for such a roll-out in routine practice would be justified on the basis of the present study, if the results indicate that the approach improves quality of care. If use of algorithms for interpretation of the glucose profile results in improved quality of care, then all primary care providers would be given the software, and it would also be made available to endocrine/diabetes specialists. If the present results indicate improvement in clinical outcomes in some categories of subjects but not others, the present system would be modified.

In view of the costs of complications of diabetes, if the present results demonstrate that the CDMP (with or without CADS) results in improved quality of care, then the Principal Investigator will be in position to advise the U.S. Army Surgeon General to disseminate similar programs to all Army treatment facilities. The number of individuals who might be covered in such a "roll-out" could be expected to number conservatively above 50,000. We would submit the results of the present study for publication in a major peer reviewed journal. We would provide all necessary information for individuals, groups or health care systems to initiate similar programs at their facilities, and make recommendations about the most efficient manner for monitoring the impact of the program.

KEY RESEARCH ACCOMPLISHMENTS:

- CADS development is near completion after initial focus groups, which included primary care providers, reviewed the algorithms and sample cases.
- Algorithms have been developed and tested with sample cases drawn from the Diabetes Institute records.

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- Upon integration of the algorithms into the software program, further tested for usability and relevance will be conducted by a nurse practitioner in the Diabetes Institute..
- Preparation for integration into CDMP and CHCS II (AHLTA) has begun.
- Study protocol and Manual of Operations are in process of being written with finalization contingent on results from the above usability study (see #2 above).

4. Validation of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool (BAT).

Principal Investigator Deborah Birkmire-Peters, Ph.D., R. Vigersky, MD, G. Welch, MD, K. Weinger, MS Ed. D.
Co-Investigator: Stephanie Fonda, Ph.D.

The Behavioral Assessment Tool (BAT) was developed by a panel of health care experts in diabetes to assess a diabetic patient's current behaviors during routine clinic visits. The BAT is a stand-alone module within the Comprehensive Diabetes Management Program (CDMP). The instrument consists of 39 multiple-choice questions about an individual's diabetes related behaviors. Most of the BAT questions are structured to indicate high, intermediate and low risk of diabetes complications. The CDMP software program generates "alerts" based on a patient's risk level and notifies the health care provider of the patient's status. These alerts can be used to target areas for behavioral and/or educational interventions.

Given that the BAT is a new instrument with much promise as a care management tool, it is necessary to test its measurement properties, including test-retest reliability and validity. The test-retest reliability study is Part 1 of such tests and focused on a small piece of them, namely test-retest reliability. This is a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The sites are: Joslin Diabetes Center, the Diabetes Institute of the Walter Reed Health Care System, the Veterans Administration Boston Healthcare System (Jamaica Plain) (VISN1), Waianae Coast Comprehensive Health Center, The Physician Center at Mililani, Molokai General Hospital, and the Indian Health Service's Phoenix Indian Medical Center (if funds become available). The study subjects at each site will be volunteers, some recruited through healthcare provider referral.

Part 2 of such tests of the BAT's measurement properties and focuses on two types of criterion validity, concurrent validity and predictive validity. Concurrent validity is the correlation between a measure and an external criterion at the same point in time. Predictive validity is the correlation between a measure and an external future criterion. To establish the concurrent validity of the BAT we will examine how study subjects' responses to its questions correlate with the following: a) their responses to similar questions in other questionnaires administered at the same time; b) recent self-report physical activity and food "logs"; c) a cotinine test (to assess smoking status); and d) concurrent health-related factors obtained from their medical records, including current or recent hemoglobin A1c (A1c), current or recent Body Mass Index (BMI), current prescribed medications, and current health conditions. To establish the predictive validity of the BAT we will assess how study subjects' responses to BAT questions (and subjects' risk stratification scores) correlate with their future health-related factors, namely health-related factors at six months and twelve months after the BAT administration completed at the beginning of the study. The health-related factors we will examine include: new A1c ; new BMI; adherence to recommended foot and eye exams in the intervening period; number of hospitalizations, number of hospital days, and number of emergency room visits in the intervening period; new medications; frequency of provider use and type of provider use in the intervening period; and new health conditions.

Both Part 1 and Part 2 have the overall goal of suggesting approaches to modify the BAT in response to what is learned from the data collection and analyses.

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Study Objectives:

Long term objective: To develop a reliable and valid instrument to assess diabetic patients' current behaviors. The instrument should be both efficient and user-friendly, providing health care providers patient information to guide behavioral and/or educational interventions.

Specific objectives:

1. To determine the reliability of the BAT. Specifically, the test-retest reliability and the internal consistency of each sub-section will be determined.
2. To validate the questions in each sub-section against established questionnaires and inventories that assess measures of behavior corresponding to the sub-sections in the BAT (construct validation).
3. To assess the relationship of scores on the BAT and HbA1c measures (predictive or criterion validation).

KEY RESEARCH ACCOMPLISHMENTS:

- Two study protocols have been written: "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool" and "An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool."
- Both study protocols have been reviewed and approved by the Joslin Diabetes Center Committee on Human Studies, and the USAMRMC Human Subjects Research Review Board (HSRRB), the local VISN 1 IRB, and the Walter Reed Army Medical Center HUC/IRB.
- Part 1 (Test-retest reliability studies) has been completed at the Joslin Diabetes Center, the Boston Veterans' Administration Hospital, and the Diabetes Institute at WRAMC.
- 41 patients (recruitment goal 42 patients) completed the study at WRAMC.
- Data analysis is pending.
- Once the WRAMC data has been analyzed and the study has been completed at the Hawaii sites, findings from all sites will be aggregated and examined to determine if test-retest reliability is invariant across sites.
- WRAMC, the Boston VA, and the Joslin Diabetes Center are recruiting patients for Part 2 (Validity) at the time of this report.
- Once the study has been completed at all participating sites, the BAT data will be aggregated and examined to determine whether these types of validity are invariant across sites

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5. Deployment of JVN Telehealth CDMP Application into the Department of Defense HealtheForces.

Robert Vigersky MD, and Sven-Erik Bursell PhD

KEY RESEARCH ACCOMPLISHMENTS

- Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) completed in May 2005.
- Diabetes Institute staff at WRAMC received CDMP training in June 2005.
- Technical problems within CDMP and deployment of AHLTA in September, 2005 postponed the beginning of the study to July 2006 (see 2).
- Replacement of HeF-ICDB with AHLTA likewise required integration of CDMP into AHLTA, a system that was not designed to incorporate stand alone clinical modules.
- Integration into AHLTA is being investigated and a three-stage plan for integration has been initiated after discussions with representatives of the Office of the Surgeon General of the Army. .

Conclusion

Diabetes mellitus is a significant cause of morbidity and mortality in the United States, and the leading cause of new blindness, chronic kidney disease, and non-traumatic amputation in the working-aged American population. Strategies are in place that, based on solid clinical and scientific evidence, can significantly reduce complications of diabetes through timely treatments and appropriate management. Unfortunately, less than 50% of patients with diabetes obtain appropriate medical care. Additionally, there are nearly 8 million Americans with diabetes who are unaware of their condition.

The Joslin Vision Network is a telemedicine initiative that has the potential to bring the highest quality care to all patients with diabetes. The JVN Telehealth program is a web-based interactive telemedicine application that can systematize the organization of disease and care management, that centralizes the patient in the care process, that can impact the ability of diabetic patients to more effectively manage their diabetes, improve their metabolic control, reduce the level of emotional stress associated with managing diabetes, and reduce the incidence of complications through implementation of the CDMP program.

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